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Elve, Maria Alexandra

Title

INVERTED STENT CUTTING PROCESS

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## REPLY BRIEF TO EXAMINER'S ANSWER

Mail Stop Appeal Brief - Patents Assistant Commissioner for Patents PO Box 1450

Alexandria, VA 22313-1450

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, 2010. August JoAnn Lindman

Dear Sirs:

Pursuant to 37 C.F.R. § 41.41, Appellants hereby submit this Reply Brief in furtherance of the Notice of Appeal filed on November 11, 2009, the Notice of Panel Decision from Pre-Appeal Review dated mailed January 26, 2010, the Appeal Brief filed on March 22, 2010, and the Examiner's Answer mailed June 23, 2010. Appellants authorize the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$540 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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## I. TABLE OF AUTHORITIES

NONE

## II. STATEMENT OF ADDITIONAL FACTS

NONE

### III. ARGUMENT

- A. CLAIMS 1, 5, 7-8, 11-17, AND 19 ARE PATENTABLE OVER ACCIAI ET AL. (U.S. PATENT NO. 5,855,802) IN VIEW OF PACETTI ET AL. (U.S. PATENT NO. 6,695,920), McCOY (U.S. PUBLISHED PATENT APPLICATION NO. 2003/0234243), AND APPLICANTS' ADMITTED PRIOR ART (AAPA) UNDER 35 U.S.C. 103(a)
  - 1. All words in a claim must be considered in judging the patentability of that claim against the prior art.

#### Acciai discloses:

"A method for forming a tubular article having a perforated annular wall, such as a surgical stent, includes coating the exterior and interior cylindrical surfaces of a tubular member with a photoresist, exposing selected portions of the photoresist coated surfaces to light, developing the coating, and then etching the coating to remove unexposed portions of the coating and immediate underlying portions of the annular wall, thereby forming a tubular article having a wall structure defined by a skeletal framework. An apparatus for exposing a light-sensitive coating to a tubular article includes means for rotating and translating the article with respect to a light source, along a longitudinal axis and simultaneously exposing aligned portions of the interior and exterior cylindrical surfaces of the tubular member." (Abstract; emphasis added.)

Each of the rejections errs in relying upon significant modifications of the Acciai apparatus and methods disclosed therein which require impermissible alteration of the principle of operation of apparatus and methods disclosed by Acciai. (MPEP § 2143.01 Part VI.)

Further, each of the proposed modifications would render the resulting apparatus unsatisfactory for its intended purpose of simultaneously exposing a photoresist in a manner such that those portions of the workpiece of Acciai which are exposed to laser illumination are retained in the finished article while those regions of a workpiece which are exposed to laser illumination in the modified apparatus and methods is removed. (MPEP § 2143.01 Part V.)

Note that the bifurcated optical system and method of Acciai simultaneously expose aligned portions of the interior and exterior cylindrical surfaces without removing any material as a result of said laser light exposure. Material removal only occurs in a subsequent etching process which follows development of the interior and exterior photoresist patterns. Although it is not explicitly disclosed in Acciai, it is believed that the development and etching steps occur after the workpiece has been removed from the laser exposure system to avoid damage to the sensitive optical elements by the harsh chemicals used for etching.

Any system which modifies the apparatus of Acciai in a manner which results in the removal of material by laser cutting from a precursor tube to a stent is believed to require an impermissible alteration of the principle of operation of Acciai in which the laser only exposes a photoresist and results in no removal of material from the precursor tube by the action of the laser.

In the Background of the Invention, Acciai teaches that the prior art employs "very high levels of plastic deformation" and "high localized heating" which undesirably work hardens the material and recrystalizes the wire, causing further damage to the wire's material. Exposure of a photoresist and subsequent etching avoid both mechanical strain and high temperature processing.

As acknowledged by the Examiner, "Acciai et al. does not teach all the elements mounted to one table, the coupling of the linear and rotary motors, the presence of guides, the workpiece below the motor(s), direct cutting using the laser, or the use of a coolant." (See the third paragraph of page 4 of the Examiner's Answer and the first paragraph of page 3 of the Final Office Action.) Other elements, such as a laser/water jet hybrid to be discussed below, are also missing from the disclosure of Acciai. The Examiner asserts that Pacetti et al., McCoy, and Applicants' Admitted Prior Art (AAPA) teach various elements of the claims. "Applicants' Admitted Prior Art" would be better characterized as Appellants' own disclosure of a useful component of the inventive apparatus.

McCoy impermissibly modifies the photoresist exposure system of Acciai by replacing simultaneous low energy resist exposures using a bifurcated optical system and subsequent etch system with a single beam directed to a single surface laser ablation system which ignores the teaching that high temperatures are to be avoided. Instead, McCoy teaches the use of a single beam laser system having a coaxial jet of pressurized oxygen which is said to react 'with the metal to assist in the cutting process very similar to oxyacetylene cutting'. (Page 2, paragraph [0015].)

Further, McCoy impermissibly inverts the removal process of Acciai by removing regions of the workpiece which <u>are</u> exposed to laser illumination while the etching process of Acciai removes those portions of the workpiece which <u>are not</u> exposed to laser illumination. Further still, the high power laser ablation system of McCoy would render the photo resist exposure system of Acciai unsatisfactory for producing a stent for at least the reason that the exposed resist, as well as the underlying metal, would be ablated by the laser of McCoy and the remainder of the metal would be removed by the etching process of Acciai following development of the exposed photoresist layers to expose metal to be removed. Accordingly, one of ordinary skill in the art would not be motivated to combine the disclosures of Acciai and McCoy as suggested by the Examiner.

Further, the Examiner, in her Answer, has asserted that Appellant have argued that McCoy does not teach a coolant as required by claim 1. Instead, Appellants have responded to the Examiner's earlier proposed motivation for combining the disclosures of Acciai and McCoy. The McCoy reference had been advanced as supplying a multi-axis laser apparatus for the fine cutting of tubing and a water system to remove debris falling into the interior of the cut tube and to push portions of the cut tube into a parts catcher. Appellants have noted that the apparatus of Acciai generates no debris as a result of the exposure of photoresist coatings present on the interior and exterior of a tube to laser light, said exposure occurring simultaneously at both surfaces as the result of a bifurcated optical system.

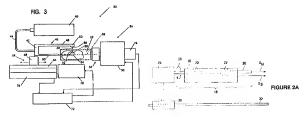
The operation of Acciai requires that the exposed photoresist remain present on the tube following removal of unexposed portions of the photoresist layers in order to prevent the etchant employed from undesirably removing material therebetween during a <u>subsequent</u> etching step. In the absence of generated debris, there is no motivation to

provide a system of McCoy, said system including a flow of water to remove nonexistent debris. As correctly noted by the Examiner, there is no "coolant" in independent claims 1 and 13. (There is a fluid passed through the workpiece in dependent claim 17.) The debris removing "water system" of McCoy, characterized by the Examiner's Answer as "a laser cutting system that uses water" is not a laser/water jet hybrid as recited in claims 1 and 13 and as disclosed in the pending application as a component of the inventive apparatus. As noted before, the use of a cutting laser, which might generate debris, is an impermissible alteration of the principle of operation of Acciai and would render the apparatus unsatisfactory for exposing the photoresist layers as taught by Acciai.

Note that the Acciai specifically teaches:

"It is important that the exposed pattern on each of the surfaces of the tubular article be aligned, i.e., that the respective patterns are identical mirror images of one another and in complete registration with each other so that an exposed area on the outer cylindrical surface directly overlays an identical exposed area on the interior cylindrical surface." (Col. 3, lines 38-44; emphasis added.)

This is in contrast an apparatus which would result from the combination of Acciai with Pacetti. Whereas Acciai takes pains to ensure precision alignment of a bifurcated optical system with both the interior and exterior surfaces of a workpiece and requires access to the opposing interior surface as illustrated in Fig. 3, reproduced below left for convenience, the exterior spray coating mandrel of Pacetti provides neither function. See Fig. 2A of Pacetti upon which the Examiner relies in the Examiner's Answer, also reproduced below right for convenience.



It is readily apparent that the mandrel 20 of Pacetti (above right) both blocks access to the upper interior of the workpiece 10, where the optical system of Acciai exposes the interior photoresist, and lacks the positional accuracy required for precision exposure of the photoresist of Acciai. Additionally, as discussed previously in the prosecution history, the support of large I.D. workpiece 10 on small gear members 22 allows the workpiece to translate longitudinally and to rock laterally in a manner which would preclude maintaining focus and alignment of the pattern to be exposed on the interior and exterior surfaces of the workpiece. Further, in the configuration of Fig. 2A as cited by the Examiner, the translation motor 28 of the spray coating apparatus of Pacetti is not attached to a second surface of base for a laser system and the motor 28 is mounted below the rotary motor, not above it as recited in the claims. Accordingly, one of ordinary skill in the art would not be motivated to abandon a fully functional support/positioning apparatus of Acciai, which provides all functions required by Acciai, in exchange for the mandrel of Pacetti, which is said by the Examiner to minimize manufacturing real estate, provide guiding support components, and/or providing "articles for motion", when the apparatus of Pacetti is functionally unsatisfactory for the precision alignment and interior access required by Acciai's bifurcated optical system. As noted above. Acciai has emphasized the importance of alignment in achieving the desired result.

The Examiner has correctly noted that the references do not need to be physically combinable; however here the elements are readily combinable. The resulting combination is, however, unsatisfactory for the purpose of Acciai; fails to provide a motivation for the proposed combination; and fails to render obvious the arrangement of components found in the claims. The stent positioning components of the system of Acciai do not appear to have identified deficiencies which would be overcome by the disclosed (incorrect) orientations of imprecise positioning components taught by Pacetti. The photoresist exposure method of Acciai does not generate debris and thus does not need to be concerned with arrangements which minimize accumulation of debris on lower components. One of ordinary skill in the art would not be motivated to substitute inferior elements for functional ones.

Accordingly, the Examiner errs by proposing to replace a photoresist exposure apparatus having a bifurcated optical system, said system not being designed to remove material, with the direct, single beam oxygen assisted material cutting laser system of McCoy and to implement the combination by replacing the precision transport systems of Acciai with the imprecise, lumen blocking workpiece support mandrel of Pacetti.

Further, the reference referred to by the Examiner as "Applicants' Admitted Prior Art" identifies a source for a component of Appellants' apparatus, said component providing features believed not previously to have been identified as desirable for use in an apparatus for cutting stents having the recited features. Both pending independent claims recite a "laser cutting system includes a laser/water jet hybrid" not found in Acciai, Pacetti, or McCoy, and only identified by Appellants as a component of their system. In the laser/water jet combination disclosed as a component of the pending application, the laser beam is confined by water thereby excluding the oxygen stream upon which McCoy depends for enhanced cutting by an oxidative process. Accordingly, one of ordinary skill in the art would not have been motivated to use the laser system of "Applicants' Admitted Prior Art" prior to the publication of the pending application and would not have used the laser in the proposed combination of components selected from the disclosures Acciai, Pacetti, and McCoy for the reason that the water stream would render the cutting laser of McCoy less effective by excluding oxygen from the heated workpiece.

For at least these reasons, as well as others discussed in greater detail in the Appeal Brief, one of ordinary skill in the art would not have been motivated to modify the photoresist exposure system of Acciai by replacing the bifurcated laser exposure system with a single beam, oxygen assisted cutting laser of McCoy to cut a workpiece which is neither longitudinally nor laterally positioned with precision by a support system of Pacetti. The Examiner has failed to identify references which teach all the claim limitations found in claims 1 and 13, as is required to establish a *prima facie* case of obviousness and has failed to provide necessary motivation for the combination of those elements which have been identified. Appellants respectfully request that the rejections of independent claims 1 and 13 be overruled.

2. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.

Claims 5, 7-8, 11, 12, 14-17, and 19, which depend from nonobvious independent claims 1 and 13 respectively, also are believed to be nonobvious and Appellants respectfully request that the rejections be overruled.

In the Examiner's Answer, the Examiner appears to assert that Appellants' discussion of the disclosures of the references is limited to "attacking the references individually". In any discussion of a combination of references, it is appropriate and often necessary to point out that the references do not disclose what they are asserted to disclose and further to use the disclosure of the references to attack not the combination, but rather the motivation to combine a list of elements in the manner proposed by the Examiner. Where an Examiner has arrayed a plurality of references it is appropriate to note that an intermediate sub-combination of one or two references does not include one or more of the missing elements. This requires characterization of the individual references which contribute to the sub-combination. For example, it is proper to note in passing that the combination of Acciai and Pacetti does not include various elements such as a laser/water jet hybrid because neither Acciai nor Pacetti include a laser cutting system of any kind.

Similarly, it is proper to note that Acciai does not teach all elements mounted on one table; Pacetti does not teach all elements mounted on one table; and/or that McCoy does not teach all elements mounted on one table as a precursor to noting that Acciai, in view of Pacetti and McCoy, does not teach all elements of the claims mounted on one table. This is not an attack on the individual references, but rather is no more than taking notice of the deficiencies of the references as applied to the claim limitations.

The Examiner further has noted that elements selected from a list of elements found in the various references, including Applicants' disclosure, may be combined to create a stent cutting apparatus capable of forming a stent. While this arguably is true, the Examiner errs by focusing upon an achievable outcome, the production of a stent by alternate means: "a proper stent would be produced" (page 12 of the Examiner's Answer), rather than upon the claimed apparatus and the extensive modifications to the

apparatus and principle of operation of the primary reference, Acciai, which would be required to create the claimed apparatus as well as the lack of motivation for those modifications.

B. CLAIMS 1, 5, 7-8, 11-17, AND 19 ARE PATENTABLE OVER ACCIAI ET AL. (U.S. PATENT NO. 5,855,802) IN VIEW OF PACETTI ET AL. (U.S. PATENT NO. 6,695,920), MCCOY (U.S. PUBLISHED PATENT APPLICATION NO. 2003/0234243), AND KRANZ (U.S. PATENT NO. 6,197,047) UNDER 35 U.S.C. 103(a).

In rejecting claims 1 and 13 as discussed above, the Examiner again errs in attempting to rely upon the combination of Acciai, Pacetti, and McCoy as discussed above and in the Appeal Brief; however in this rejection, the Examiner attempts to overcome the lack of a disclosure of a laser/water jet hybrid by turning to the disclosure of Kranz.

Kranz is characterized by the Examiner as providing a "water laser". That term is not found in the pending application or in Kranz. It is presumed that the Examiner intended to provide a laser/water jet hybrid which is found in independent claims 1 and

13. The cited portion of Kranz is:

"In a preferred embodiment of a stent according to the invention the partition lines are of a width substantially corresponding to that of a clean incision when the surface is severed by means of a cutting beam, e.g. a cutting jet of water preferably a laser beam. Narrow partition lines give the non-expanded stent particularly high stability." (Col. 2, lines 28-33; emphasis added by the Examiner.)

Appellants believe that the cited passage includes a typographical error in that it appears to be missing at least "or" between "... water" and "preferably ..."

This may be seen by comparison with the parallel text at column 6, lines 1-5:

"It is possible to use a water jet cutting process to produce the partition lines. However a laser beam is preferably used as the cutting beam, firstly because very high cutting precision can be obtained, and secondly because the mechanical strains on the stent are minimized." Accordingly Kranz does not overcome the deficiencies of Acciai in view of Pacetti and McCoy with respect to the remaining missing elements of claims 1 and 13 as discussed above. Appellants respectfully request that the rejections of independent claims 1 and 13 over Acciai in view of Pacetti, McCoy, and Kranz be overruled.

Claims 5, 7-8, 11, 12, 14-17, and 19, which depend from nonobvious independent claims 1 and 13 respectively, also are believed to be nonobvious and Appellants respectfully request that the rejections be overruled.

C. CLAIMS 6 AND 18 ARE PATENTABLE OVER ACCIAI ET AL. (U.S. PATENT NO. 5,855,802) IN VIEW OF PACETTI ET AL. (U.S. PATENT NO. 6,695,920), MCCOY (U.S. PUBLISHED PATENT APPLICATION NO. 2003/0234243), AND (APPLICANTS' ADMITTED PRIOR ART (AAPA) OR KRANZ (U.S. PATENT NO. 6,197,047)), AND FURTHER IN VIEW OF MAGNANTE (U.S. PATENT NO. 6,086,204) UNDER 35 U.S.C. 103(a).

As discussed above and elsewhere, Acciai in view of Pacetti, McCoy, and (AAPA) or Kranz fails to render obvious claims 1 and 13. The addition of Magnante, relied upon only for a granite base not found as a limitation of either claim 1 or 13, does not overcome the deficiencies of the previously cited references as applied thereto. Claims 6 and 18, which depend from nonobvious independent claims 1 and 13 respectively, also are believed to be nonobvious and Appellants respectfully request that the rejections be overruled.

#### D. CONCLUSION

For at least the reasons stated above and in the Appeal Brief, claims 1, 5, 7-8, 11-17, and 19 are nonobvious over Acciai in view of Pacetti, McCoy, and either Kranz or Appellants' disclosure; claims 6 and 18 are nonobvious over Acciai in view of Pacetti, McCoy, and either Kranz or Appellants' disclosure and further in view of Magnante; and the Examiner's rejections of claims 1, 5-8, and 11-19 under 35 U.S.C § 102 and § 103 should be overruled.

Respectfully submitted,

Date: Angust 20, 2010

Glenn M. Seager, Reg. No. 36,926

CROMPTON, SEAGER & TUFTE, LLC 1221 Nicollet Avenue, Suite 800

Minneapolis, Minnesota 55403-2420

Glenn.Seager@cstlaw.com

Tel: (612) 677-9050 Fax: (612) 359-9349